

## MEMORANDUM

DATE: APRIL 20, 1993

RE: CONFERENCE ON THE RISK ASSESSMENT PARADIGM AFTER TEN YEARS: POLICY AND PRACTICE THEN, NOW, AND IN THE FUTURE, APRIL 5-8, 1993, WRIGHT-PATTERSON AIR FORCE BASE, OHIO

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This conference was intended to provide a 10-year perspective on use of the risk assessment paradigm, which was first introduced by the National Academy of Sciences in 1983. The essential aspects of this paradigm are that it distinguished identification and description of risk from the process of doing something about risk. This is the distinction between risk assessment versus risk management. On the risk assessment side, hazards are identified and dose-response relationships are determined. This information is evaluated, together with exposure data, in order to "characterize" the risk. On the risk management side, regulatory and policy decisions are made based on the risk characterization data, but also based on the available options for control of the hazards, and based on an evaluation of several nonrisk types of issues relating to, for example, economics, politics, statutory and legal considerations and various social factors.

Smoking or ETS was not a theme at the conference, except in the presentation by Steven Bayard (U.S. EPA), which summarized the EPA risk assessment on ETS and lung cancer and respiratory disease in children. Bayard's presentation is discussed later in this memo.

The conference consisted of six sessions, each composed of five or more presentations given on a morning or an afternoon. Session I consisted of presentations centering on basic descriptions of risk assessment and risk management, using the paradigm set forth in 1983 by the NAS. Session II consisted of presentations in which the paradigm was used in evaluating specific potentially toxic exposures (e.g., selenium, beryllium, dioxin and others). It was in this session that Steven Bayard reviewed the EPA's risk assessment on ETS. Session III was titled "Where the Paradigm Needs Change." Despite this title, there was no substantive criticism of the paradigm. Presenters and audience alike seemed to be in agreement as to the usefulness of the NAS paradigm. Sessions IV and V were both "scientific" sessions, presenting discussions of various chemicals, exposures and disease processes. The information in these presentations covered physiological

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responses to chemical exposures, theories of cancer development, pharmacokinetic theories and data and other basic science information related to toxicology. Session VI dealt with communication theory as it would be applied to communication of information on risk to the public.

The most notably consistent focus in the conference was environmental pollution and hazardous waste clean-up, with a particular focus on clean-up of military bases. The major sponsoring organizations of the conference were, in fact, the toxicological research labs of the three major branches of the Armed Forces. In the opening comments, it was noted that there were about 350 people signed up for the conference.

Attendees at the conference were provided two bound groups of materials. One contains biographical sketches and abstracts of most of the presentations, including the poster presentations. The other was published as an EPA document, and contains, in addition to biographical sketches of most of the presenters, complete conference papers of most of the major presentations. I am sending these to the file.

#### Steven Bayard's Presentation

Steven Bayard handed out copies of the slides used in his presentation, and a copy of these is attached to this memo. Apparently most of these overheads were taken directly from, or are obviously based on, the published EPA risk assessment on ETS. Bayard opened by characterizing the importance of the EPA risk assessment in terms of three aspects. First, there is an enormous database related to ETS. Second, there is a very large epidemiology database at "true environmental levels." Third, everyone is exposed to ETS. With regard to this last point, Bayard emphasized that "ETS is the only compound for which cancer has been shown at typical environmental levels." For other compounds which have been labeled as "known human carcinogens," the concern only arises in special exposure situations, particularly occupational exposures.

Bayard characterized the "weight of the evidence" for the report's claims concerning ETS and lung cancer by citing: data on dose-response; similarity of mainstream smoke and ETS; the supporting evidence from animal bioassays; and the biomarker evidence of ETS uptake by nonsmokers.

Bayard briefly summarized 30 epidemiological studies on ETS and lung cancer, and endorsed meta-analysis. ("The real benefit of meta-analysis is that you can include both positive and negative studies.") He also referred to the EPA risk assessment's use of a

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"quality ranking" of the studies based on a "tier classification of weighting factors." He concluded by stating his judgment that both qualitative and quantitative evaluations of the 30 studies show the same results -- namely, an association of ETS and lung cancer.

Following Bayard's presentation, the session chairman only allowed time for one comment from the audience. This audience comment expressed a need to emphasize that mainstream smoke also contributes in an important way to ETS in addition to sidestream smoke, and that there was a need to look at the combined effect of both active and passive smoking in the same individual.

I made a few personal observations of Bayard's presentation, as follows. His presentation, I think, is fairly described as somewhat disorganized, and it had an off-the-cuff quality and I think most people would agree that he spoke much too fast. It may also be notable that he said nothing about a variety of issues which might be of interest to the industry. For example, he said nothing about the use of 90% confidence intervals in statistically evaluating the ETS/lung cancer studies. Nor did he discuss weaknesses in the data related to confounding. In fact, he emphasized the strength of the data, due to numerous studies of various designs in various countries coming up with basically the same results.

Bayard was a fairly visible figure at the conference. He struck me as being quite personable and outgoing. He was an active participant in many of the discussions following presentations on a wide variety of topics. Often he asked detailed statistical or computer-related modeling or methodological questions, which appeared to reflect a sophisticated technical expertise in risk assessment methods.

Following Bayard's presentation, during a coffee break, I overheard one attendee compliment Bayard on his presentation. Bayard's response was something to the effect of "yes, but did I convince you." That was the end of the interchange. Perhaps Bayard's comment may be an indication that he had met with skepticism in previous presentations of the EPA's risk assessment on ETS.

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The remainder of this memo discusses some of the other presentations of potential interest.

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#### Barnes

Donald Barnes (U.S. EPA) provided an overview of the NAS/NRC paradigm introduced in 1983. He endorsed it as having "served us well" and described it as "flexible." He reviewed the basic aspects of risk assessment versus risk management. The EPA was one of the first groups to pick up this paradigm, and incorporated it into the EPA's cancer risk assessment guidelines. He further endorsed the paradigm as being very useful in providing a structure for disciplined decision-making, and helping to allow establishment of priorities.

Barnes closed his presentation by noting several things to look for in the future. First, he said that we should watch for an NAS update of its 1983 "Redbook." Second, he raised the question of what the new administrator of the EPA will do. Barnes said that new cancer risk assessment guidelines are anticipated. Third, he raised the question of what will Congress do. He specifically referred to Senate Bill S-110. This bill forces risks to be ranked and to establish the most cost effective methods of dealing with them. It establishes committees for these purposes.

#### Keenan

Russell Keenan is affiliated with McLaren/Hart Environmental Engineering. He spoke generally about "exposure assessment." He emphasized the importance of this topic by observing that "you can't regulate toxicity, only exposure."

A central aspect of Keenan's presentation was the changing exposure standards given by the EPA. In particular, he cited standards from the EPA in 1986, 1989 and 1992, each of which reflected a different approach. These are as follows:

EPA, 1986 -- MEI -- maximally exposed individual  
EPA, 1989 -- RME -- reasonable maximal exposure  
EPA, 1992 -- HEE -- high end exposure.

#### Farland

William Farland (U.S. EPA) gave a presentation on the EPA's reexamination of its position on dioxin. His presentation, titled "Components of the Dioxin Risk Reassessment," covered types of information involved in the dioxin reassessment and how dioxin might exert its effect biologically. The EPA's reassessment of dioxin has a heavy focus on data relating to biological mechanisms.

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Farland stated that the reasons for EPA's reassessment of dioxin were as follows:

(1) "Evolving science," as reflected, in particular, in a Banbury Conference, in October 1990.

(2) A NIOSH study in January 1991 (1/24/91, NEJM).

Farland characterized EPA's reassessment as being "open and participatory," as reflected in (1) the use of external authors, (2) public meetings, for example, in November 1991 and in April 1992 and (3) the use of a public peer review process.

Farland said there is a new draft relating to the dioxin reassessment coming out in the next couple of months. The aim is for the EPA to complete the entire dioxin review process by the fall of 1993 and to release a report sometime in early 1994. The reassessment will provide a biologically-based assessment of effects, rather than a simple extrapolation downward from a few tumors in mice. In his view, whatever the "number" eventually arrived at, the data and processes underlying its determination will be very different than for the previous number. (By this, Farland was emphasizing the importance of the biological mechanisms data that will be incorporated into the dioxin review process.) Farland also commented that the toxicological risk associated with dioxin may be "about the same" as previously judged by the EPA.